Applicant: Samantha K. Holme et. al.

Serial No. 10/719,602

Before discussing the details of the Office Action, a brief discussion of the

claimed invention is deemed helpful to understand the differences between the claimed

invention and that of the prior art relied on in the Office Action. The claims of the

present Application are directed to a chewing gum composition that is useful for

removing stains on dental surfaces when placed in the oral cavity, and then chewed by

the consumer. The chewing gum composition as claimed has two essential aspects,

which in combination distinguish over the prior art.

The first aspect is that at least two stain removing components are employed in

the chewing gum composition. These stain-removing components are selected from a

peroxide compound, a polyphosphate, and an anionic surfactant. The second aspect is

that the stain removing components must not be materially bound to the gum base, in

order to achieve the objects of the invention. It is the combination of these two aspects

that allows the applicants to achieve desirable stain-removing properties that are not

obtained when only one stain-removing agent is employed, and/or when one or more of

the stain-removing agents are materially bound to the gum base.

Page 19, lines 4-11 of the present Application, identifies the importance of

enabling the release of the stain-removing agents from the chewing gum composition

into the oral cavity. Several ways are provided for preventing the stain-removing agents

from being materially bound to the gum base. As indicated at page 20, lines 4-10, the

stain-removing agents can be added into the center-fill of a center-filled chewing gum

composition, which does not contain gum base. Thus the stain-removing agent is kept

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apart from the gum base, and therefore cannot become materially bound thereto.

Another way of preventing undesirable binding of the stain-removing agents to the gum

base is to place the stain-removing agents in the coating of a chewing gum composition

containing a core and a coating, where the core contains the gum base.

However, many chewing gum compositions do not contain a hard coating or are

not the center-fill variety. The problem is that when an anionic surfactant is added to

such compositions, they serve as softeners to soften the gum base, making the chewing

gum composition more "chewy". The prior art teaches that softeners are added directly

to the gum base to provide the softening effect.

Thus, the present invention requires that the two or more stain-removing agents,

regardless of where they are located, must not be materially bound to the gum base. If

they are, they cannot be effectively released from the chewing gum composition to

perform a stain-removing function, even though they anionic surfactants may effectively

perform a "softening" function.

The present invention requires at least two stain-removing agents. Applicants

have previously shown through reference to standard, well-accepted test procedures

that there is an unexpectedly enhanced effect when two or more of the claimed stain-

removing agents are incorporated into the chewing gum composition as compared to a

Page 4 of the Office Action questions the results single stain-removing agent.

First, the Office Action states that it cannot be presented in the Specification.

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determined if the effects would also be seen when a chewing gum comprises the stain-

removing components. Second, the results are alleged not to be commensurate in

scope with the instant claims, since they use only a representative example of peroxide,

an anionic surfactant and polyphosphate at specified amounts. Applicants respectfully

traverse the criticism of the experimental data.

As previously indicated, one of the test procedures disclosed in the present

Application, showing a stain-removing result, is a well-established protocol for this

purpose. One of ordinary skill in the art would recognize that the procedure followed in

the present Application is a valid indication of the stain-removing effect of the test

compositions. These test compositions were used to treat stains appearing on

hydroxyapatite discs (Examples 1 and 2). However, Example 3 provides a stain-

removal test model in which gum samples containing the stain-removing composition

were masticated by a chewing machine that was outfitted with stained bovine teeth,

providing chewing surfaces to simulate the top and bottom teeth in a human mouth

(page 37, lines 6-8). Accordingly, Applicants not only tested the stain-removing

composition in a standard in vitro testing procedure, but also achieved the same results

when utilizing the stain-removing composition within a chewing gum. Therefore, the

criticism of the test results based on the disclosed experimental data is improper.

Applicants have explained in the Specification and during prosecution of the

present Application that a key to the claimed invention is the availability of the stain-

removing agents to perform a stain-removing function. To be available for this purpose,

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the stain-removing agents must not be materially bound to the gum base. Applicants

have provided several ways that this can be made possible in the manufacture of a

chewing gum composition. Given that Applicants have taught how to construct how to

construct a chewing gum composition with two or more of the claimed stain-removing

agents, so that they are able to perform a stain-removing function, and given that the

stain-removing agents must be available in a stain-removing effective amount, the

examples shown in the present Application are clearly sufficient to prove efficacy of the

claimed invention.

Applicants have provided examples of a stain-removing effective amount utilizing

two or three of the stain-removing agents, and have shown surprising and unobvious

results when compared with a control (water) and the use of only a single stain-

Applicants have used representative amounts of each of the removing agent.

components and certainly amounts that fit within the ranges provided in the dependent

claims. Applicants are not required to demonstrate efficacy over the full possible range

of the stain-removing agents unless there is a sound basis for doing so. The Office

Action has presented no reason why one of ordinary skill in the art would not expect

similar results with other stain-removing agents within the three categories of stain-

removing agents set forth in claim 1.

It is therefore submitted that the surprising and unexpected use of two or more of

the stain-removing agents set forth in the present claims, when used in a stain-removing

effective amount, is sufficient to support the claims as they now stand. Unlike

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unpredictable scientific disciplines such as cancer treatment, data presented in the

present Application in support of a surprising and unobvious result would be expected

for the full range of Applicants claims, in the absence of any evidence to the contrary.

As we have shown, the present invention relies on the combination of two or

more stain-removing agents in effective amounts, and requires that they not be

materially bound to the gum base. As we will further show, references relied on in the

latest Office Action do not teach or suggest this combination of inventive aspects, nor

would reasonable motivation or common knowledge enable one of ordinary skill in the

art to reach the claimed invention.

Referring to the Day reference, the Office Action acknowledges that

polyphosphates are distributed within the gum base, and indicates at page 11, lines 35-

40, that the polymeric surface active agent is present in the gum base, the outer coating

Applicants do not disagree with this characterization of the reference. or both.

However, the Office Action appears to allege state that whitening agents and

surfactants are active ingredients that are disclosed to be used in combination with the

polymeric active material, and that such agents are not added to the gum base. The

position taken in the Office Action is untenable.

Applicants have identified potassium stearate and sodium stearate (and their

combination) as a preferred anionic surfactant for use in the present invention. These

materials are identified in Day at page 8, lines 22-24, wherein it is stated that softeners

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can be employed in chewing gum compositions, and that suitable softeners include

sodium stearate and potassium stearate. Page 8, lines 32-34 clearly state that such

materials are incorporated into the gum base in order to modify the texture and

consistency properties of the gum base. "In particular, they help to soften the chew and

to maintain chew softness over an extended period of time."

The preferred stain-removing agents of the present invention (sodium stearate

and potassium stearate) are purposely incorporated into the gum base in the Day

reference to provide a softening effect. One of ordinary skill in the art would recognize

that anionic surfactants, and particularly sodium stearate and potassium stearate, have

a softening function and would not know that such materials perform a stain-removing

function. This is because when such substances are incorporated into the gum base,

they are retained in the gum base and therefore, not available to perform a stain-

removing function. It is only by Applicants discovery that when such substances are

placed in the chewing gum composition in a manner that does not allow them to be

materially bound to the gum base, that they are able to perform a stain removing

function.

While Applicants agree that phosphates are disclosed and that they may be

present in the core, the coating, or both, a fair reading of the Day reference teaches

only that a single stain-removing agent may be used in the chewing gum composition.

There is no teaching, however, of the use of two or more stain-removing agents, all of

which are required to be out of contact with the gum base, and certainly no indication

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that the use of two such stain-removing agents provides a surprising and unobvious

stain-removing effect over the use of a single stain-removing agent.

The Howard reference is stated to teach a peroxyhydrate as a stain-removing

agent. Thus, the Office Action admits that only one stain-removing agent is recognized

in the Howard reference. The Office Action then presents the argument that the present

invention mixes polyphosphates and anionic surfactants with the gum base and

therefore manufactures the chewing gum composition in the same way as Howard. The

rejection is hereby traversed, and reconsideration is respectfully requested.

The only one of the stain-removing components of the present invention

disclosed in Howard is a peroxide compound (e.g. sodium carbonate peroxyhydrate).

As indicated in column 4, lines 13-15, plasticizers or softening agents are incorporated

within a gum base. Typical softeners/emulsifiers include glycerol triacetate, which is

one of the anionic surfactants listed in claim 9 of the present Application. As shown in

Example I, the Howard preparation of a chewing gum composition shows that the gum

base is combined directly with the listed gum ingredients, which includes vegetable

glycerin (a plasticizer or softening agent, column 4, line 14). Thus, the examples teach

that a plasticizer or softening agent, including any anionic surfactants (e.g. glycerol

tristearate) is added directly to the gum base.

Therefore, Howard teaches to one of ordinary skill in the art the use of a single

stain-removing agent, and does not teach or suggest the use of two or more stain-

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removing agents, nor the importance of keeping the stain-removing agents away from

the gum base.

The Office Action suggests that the manner of incorporating the stain-removing

agents into the chewing gum composition is the same as that in the Howard reference.

This is clearly not correct. As we have shown, Howard incorporates

emulsifiers/softeners directly into the gum base. The present Application, as previously

explained, keeps the stain-removing agents in a different location than the gum base

(e.g. in the center-fill or the coating where the gum base is not present, or mixes the

stain-removing agent as one of the last steps, or preferably the last step, so that as

much of the stain-removing agent is removed from the gum base as possible). Nothing

in Howard teaches or suggests this aspect of the claimed invention.

Miskewitz teaches, like the other references, that conventional softeners,

plastricizers and emulsifiers are added to the gum base. The Office Action alleges that

surfactants are not necessarily used in the gum base, but provides no basis for reaching

that conclusion. Instead, the Office Action looks to the present Application to allege that

the compositions are made the same and therefore, the surfactant in the prior art is not

materially bound to the gum base. This line of reasoning cannot be sustained. In

observing the preparation of the product in Example III of the reference, a substantial

portion of the urea peroxide is added directly to the gum base. This is contrary to the

presently claimed invention. There is therefore no recognition in Miskewitz nor mention

of the use of two or more stain-removing agents, each of which is not materially bound

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to the gum base. The rejection based on Miskewitz is therefore improper and should be

withdrawn.

Claims 20-24, 29 and 30 stand rejected as obvious over Day in view of Sagel

(U.S. Patent No. 6,582,708). The rejection is hereby traversed and reconsideration is

respectfully requested.

As previously indicated, the Office Action previously acknowledged that Sagel

does not teach or suggest the use of a polyphosphate, or an anionic surfactant in the

manner claimed in the present Application, to give a stain-removing effect. Since only

the use of a peroxide compound is disclosed, there is no recognition of the surprising

and unobvious nature of the present invention when employing two or more stain-

removing agents. It is therefore submitted that Sagel does not add anything further to

the disclosure of Day. The rejection based on obviousness is therefore unsupported,

and should be withdrawn.

The rejection of claims 44-46 as obvious over Cherukuri (U. S. Patent No.

4,980,178) is noted, as is the application of this reference to claims 9-14, 24, 25 and 35.

However, it has been established that Cherukuri is cited solely for the purpose that

center-filled chewing gums were known in the art. As Applicants have previously

shown, Day does not disclose the combination of stain-removing agents as required in

the present claims, nor teach that all of the stain-removing agents must not be

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materially bound to the gum base. It is therefore submitted that the claims rejected based on Day and Cherukuri are free of the prior art.

In view of the forgoing, Applicants submit that the present Application is in condition for Allowance, and early passage to issue is therefore deemed proper and is respectfully submitted.

Respectfully submitted,

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